



4164-01-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2018-D-1216]**

### **Electronic Common Technical Document v4.0 Technical Conformance Guide; Food and Drug Administration Electronic Common Technical Document v4.0 Module 1**

#### **Implementation Package; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is requesting comment on the draft Electronic Common Technical Document (eCTD) v4.0 Technical Conformance Guide and the FDA eCTD v4.0 Module 1 Implementation Package. The eCTD v4.0 Technical Conformance Guide will provide specifications, recommendations, and general considerations on how to submit eCTD v4.0-based electronic submissions to the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) using the International Council for Harmonisation eCTD v4.0 Implementation Package and the FDA eCTD v4.0 Module 1 Implementation Package. The Agency is seeking comment on the eCTD v4.0 Technical Conformance Guide and the FDA eCTD v4.0 Module 1 Implementation Package for the accuracy, suitability, and appropriateness of these specifications for the submission of eCTD v4.0 submissions. These versions of the documents are not for implementation.

**DATES:** Submit either electronic or written comments by **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instruction.”

*Instructions:* All submissions received must include the Docket No. FDA-2018-D-1216 for “Electronic Common Technical Document (eCTD) v4.0 Technical Conformance Guide; FDA eCTD v4.0 Module 1 Implementation Package.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact

information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The eCTD v4.0 Technical Conformance Guide and FDA eCTD v4.0 Module 1 Implementation Package are available on FDA’s eCTD v4.0 webpage at: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm309911.htm>.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the eCTD v4.0 Technical Conformance Guide or FDA eCTD v4.0 Module 1 Implementation Package to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in

processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to these documents.

**FOR FURTHER INFORMATION CONTACT:** Jonathan Resnick, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3160, Silver Spring, MD 20993-0002, 301-796-7997; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

**SUPPLEMENTARY INFORMATION:**

I. Background

The eCTD v4.0 Technical Conformance Guide and the FDA eCTD v4.0 Module 1 Implementation Package are draft versions of the eCTD standard format. FDA will continue to only accept eCTD v3.2.2 submissions until eCTD version 4.0 is finalized. Once eCTD v4.0 is finalized, FDA will accept both eCTD v3.2.2 and eCTD v4.0 submissions for a lengthy phase-in period before eventually only accepting eCTD v4.0 submissions. FDA is requesting comments on the draft eCTD v4.0 Technical Conformance Guide and the FDA eCTD v4.0 Module 1 Implementation Package for eCTD v4.0 submissions only. After receiving comments, the Agency will update the eCTD v4.0 Technical Conformance Guide and the FDA eCTD v4.0 Module 1 Implementation Package to facilitate the Agency's future acceptance of eCTD v4.0 submissions.

The eCTD v4.0 Technical Conformance Guide will provide specifications, recommendations, and general considerations on how to submit eCTD v4.0-based electronic submissions to CDER or CBER when the Agency implements eCTD v4.0. The eCTD v4.0 Technical Conformance Guide is organized as follows:

## Section 1: Introduction

- Provides information on regulatory policy and guidance background, purpose, document control, new features of eCTD v4.0, and guidelines for an eCTD v4.0 submission.

## Section 2: Submission Contents

- Recommends and provides details on specific topics organized by their placement (by module) in the eCTD submission.

## Section 3: Combination Products

- Recommends and provides details on device combination product information organized by their placement in the eCTD submission.

## Section 4: Two-Way Communications

- Provides details on the two-way communication process.

## Section 5: Rules for Submission Tracking Information

- Provides details on the submission tracking relationships for an FDA eCTD submission.

The FDA eCTD v4.0 Module 1 Implementation Package will provide the detailed specifications to create Module 1 of an eCTD v4.0-based electronic submission for CDER or CBER. The Implementation Package will provide the technical specifications and the necessary components to create a valid FDA eCTD v4.0 submission. The Implementation Package contains the following components:

### FDA eCTD Module 1 Implementation Guide

- The technical specification for the FDA eCTD v4.0 Module 1 using the Health Level Seven Regulated Product Submission Release 2, Normative standard.

### FDA Regional Genericcode Controlled Vocabulary Files

- Includes region-specific vocabulary and the files intended for implementers to use as a computable version of the controlled vocabulary content.

## FDA Regional Module XML Samples

- Includes samples of M1 eCTD v4.0 xml.

## FDA Object Identifiers (OID) Listing

- Provides the OIDs to be used for the FDA Module 1 controlled vocabulary.

## FDA Regional Controlled Vocabulary

- Includes region-specific vocabulary and these files are intended as the human readable version of the controlled vocabulary content.

## FDA Regional Controlled Vocabulary for Transition Mapping Message DTD 2.01

- Provides a human readable version of the controlled vocabulary transition mapping for the transition from Module 1 DTD 2.01.

## FDA Regional Controlled Vocabulary for Transition Mapping Message DTD 3.3

- Provides a human readable version of the controlled vocabulary transition mapping for the transition from Module 1 DTD 3.3.

## II. Electronic Access

Persons with access to the internet may obtain the eCTD v4.0 Technical Conformance Guide and the FDA eCTD v4.0 Module 1 Implementation Package at either <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm309911.htm> or <https://www.regulations.gov>.

Dated: February 19, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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